Congress of the United States

House of Representatives

Washington, DC 20515

February 27, 2004

The Honorable G. Tommy Thompson
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Secretary Thompson:

Abbott Laboratories recently announced that it has increased the price of ritonavir, an important AIDS drug marketed under the name of Norvir, by 400%. Ritonavir was discovered under a U.S. government grant. Abbott Laboratories has indicated that only U.S. purchasers will be subject to the price increase. We ask that you take action immediately to protect American AIDS patients and U.S. taxpayers from this blatantly exploitative pricing policy. Several patient groups, AIDS providers and generic drug manufacturers have petitioned you for relief under the federal Bayh-Dole Act.

The facts in this case are extraordinary and warrant extraordinary action by the government. Taxpayer-funded research was instrumental in developing the drug, and the manufacturer's development costs were unusually low due to small, quick clinical trials and expedited government review. The manufacturer has generated more than a billion in sales revenue from the drug, yet has adopted a pricing policy that exploits and discriminates against the very taxpayers who subsidized the development of its product. Following are relevant details:

- Ritonavir was conceived in the performance of grants from the National Cooperative Drug Discovery Group for AIDS (NCDDG-AIDS), administered by the National Institute of Allergy and Infectious Diseases. Abbott Laboratories acknowledges the federal government's rights in six ritonavir and lopinavir patents..

- Abbott Laboratories' drug development costs for ritonavir were low because of the short development timeframe and the small number of patients included in clinical trials. FDA completed review and approval of ritonavir in just 70 days. FDA's review was based on three clinical trials (the longest of which lasted 48 weeks) with 1,583 patients. Abbott Laboratories began selling ritonavir as Norvir in 1996.

- By the end of 2001, cumulative Norvir sales had already exceeded $1 billion.

- Norvir is now primarily used as a "booster" of protease inhibitor regimes, and is recommended for use in conjunction with six of seven protease inhibitors used in Highly Active Antiretroviral Treatment (HAART) for AIDS.

- Abbott Laboratories announced plans last fall to increase the price of Norvir five-fold. For patients who use the most common dose (200 milligrams per day), this is an increase in the average wholesale price of $6,100 per year.

- The new pricing policy will impair competition. The manufacturer's planned price increase will apply only when Norvir is used as booster for competitors' products. Abbott did not apply this price increase to Norvir used in its own Kaletra product, a co-formulation of Norvir/Lopinavir used to treat AIDS. By applying the price increase only to its competitor's products, Abbott is seeking to unfairly increase its market share in the protease inhibitor market and distort prescribing practices.

- The manufacturer is using pricing policies to discriminate against American AIDS patients and taxpayers. Abbott Laboratories has limited the 400% price increase to the U.S. market. The manufacturer is charging U.S. consumers and third party payors four times more than foreign purchasers (including those in foreign nations classified as high income by the World Bank) for a product developed with U.S. tax dollars.

Abbott Laboratories' exploitation of U.S. AIDS patients and U.S. taxpayers demands quick and decisive action by the Bush Administration. Through Medicaid and the Ryan White Care Act programs, federal tax dollars are the largest source of funding for U.S. AIDS drugs. These programs are already facing shortfalls in funding, and are restricting access and rationing medicines. Abbott claims that ADAP programs will not face the higher prices for the existing formulation of Norvir. Even if this is true, the effects of the price hike will still be significant. First, programs operated by cities under Title I of the Ryan White Act and by non-profit treatment clinics are saddled with the full price increase. Second, price inflation that erodes private coverage increases the toll on public sector programs.

We understand that one of the applicants for the federal march-in request asked that you consider implementing an R&D requirement for those producing generic versions of a patented drug. Each generic supplier would not only pay a royalty to the patent owner, but also contribute a fixed amount to support additional research. The notion of an R&D requirement was first proposed in a 1983 case involving cisplatin, a government funded cancer drug, and again in 1997, in connection with Bristol-Myers Squibb's efforts to extend its monopoly on Taxol, another government funded cancer drug. We believe the idea of an R&D requirement deserves serious consideration as we search for ways to protect consumers while ensuring continued innovation for new medicines.

Clearly there is solid justification in this case for exercising the government's authority to maintain the accessibility and affordability of an essential medical invention. Your failure to provide relief in the case of this important AIDS drug would signal that the federal government will tolerate virtually any corporate misuse of taxpayer-funded inventions.

We support the efforts of the petitioners to make ritonavir more accessible. We hope you will carefully consider the petition before you and exercise your authority for the benefit of American AIDS patients and American taxpayers.

Sincerely,

SHERROD BROWN
Member of Congress

HENRY A. WAXMAN
Member of Congress

JAN SCHAKOWSKY
Member of Congress

ROSA L. DeLAURO
Member of Congress

BERNARD SANDERS
Member of Congress

DENNIS KUCINICH
Member of Congress